

K011431

10.

510(k) Summary of Safety and Effectiveness**JUN 11 2001**Submitter

S & C Polymer GmbH
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Dr. Jürgen Engelbrecht (Contact Person)

Date Summary Prepared: April 2001

Device Name:

- Trade Name – Resin Cem
- Common Name – Glass-ionomer Cement
- Classification Name – Cement, Dental, per 21 CFR § 872.3275

Devices for which Substantial Equivalence is Claimed:

G & C International Cooperation, *GC Fuji Lining LC*
G & C International Cooperation, *GC Fuji II LC Improved*
3M, *Single Bond*

Device Description:

Resin Cem consists of five different components, two cements with an additional Resin / Water solution, two one-component adhesives and an activator for this two adhesives.

Intended Use of the Device:

The product is used as a base or liner in prepared cavities (AC Ionomer Cem), for restorations (LC Ionomer Fill) and for reinforcing the bonding of enamel / dentine to glass-ionomer cements and other filling materials (Prime Bond Aqua, Prime Bond Ethanol). Primebond Activator functions as a catalyst (self cure).

Substantial Equivalence:

Ionomer Cem is substantially equivalent to other legally marketed devices in the United States. The Cements, the adhesives and the activator marketed by S & C Polymer functions in a manner similar to and is intended for the same use as the product marketed by G & C International and 3M.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2001

Mr. Christian Bottcher
Regulatory Compliance Officer
S & C Polymer GMBH
Robert-Bosch-Stresse 5
Elmshorn,
GERMANY

Re: K011431
Trade/Device Name: Resin Cem
Regulation Number: 872.3275
Regulatory Class: II
Product Code: EMA
Dated: May 3, 2001
Received: May 9, 2001

Dear Mr. Bottcher:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

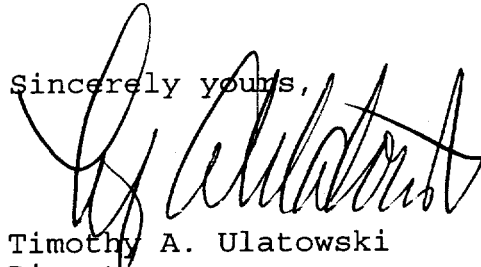
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011431

9. Statement of Indications for Use

510(k) Number (if known): K011431

Device Name:

RESIN CEM

Indications for Use:

AC Ionomer Cem:

As a base or liner in prepared cavities.
Suitable for cementing all types of crowns, inlays, veneers, bridges and orthodontic bands and brackets

LC Ionomer Fill:

Class III and V restorations, particularly for cervical erosions and root surface caries.
Restoration of primary teeth.
Core build up.

Prime Bond Aqua / Prime Bond Ethanol:

Light cure single component priming adhesive designed to reinforce the bonding of enamel and dentine to glass-ionomer cements but also to other filling materials, e.g. composites, compomers or non-precious metals.
It also can be used for priming the root canals or cementation of endodontic posts.

Prime Bond Activator:

Agent for activating (self cure) the Prime Bond Aqua and Prime Bond Ethanol.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K011431

Prescription Use: ✓

or

Over-The-Counter Use: